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November 18, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

On behalf of the Manufacturing Defendants, I write to inform the Court that the Manufacturing Defendants are serving Plaintiffs today with amended objections to Plaintiffs' document requests.[1] Accordingly, Plaintiffs' assertion that the Manufacturing Defendants' original objections to Plaintiffs' document requests were "boilerplate" and waived is moot. Should the Court entertain Plaintiffs' request to strike the Manufacturing Defendants' objections

[1] The parties did not have an opportunity to engage in a meet and confer with respect to Plaintiffs' Mylan-specific requests—plus approximately 25 additional requests pertaining to (i) DMFs and ANDA files, (ii) bioequivalence, (iii) identification of customers, and (iv) sales and pricing—until the afternoon of Thursday, November 14. The next day, Friday the 15th, the parties traveled to Philadelphia to engage in an in-person conference regarding Mylan's data management systems as required pursuant to the Court's Order of November 7, 2019. *See* Dkt. 292. Separately, the deadline for the parties to respond to the letter briefs concerning "macro" discovery issues fell on Monday, November 18. *See* Dkt. 280. Mylan therefore intends to serve its amended objections at or before this Wednesday's conference, less than a week following the completion of the Mylan-specific meet-and-confer process—a considerable feat given the level of activity and the vastness of Plaintiffs' discovery directed to the manufacturers.

notwithstanding, the Manufacturing Defendants respectfully request the Court defer argument on that brief, the Manufacturing Defendants' response to which is also being filed today, until the hearing on other discovery issues scheduled for December 11.

As set forth in the Manufacturing Defendants' amended objections and in their response brief regarding Plaintiffs' assertions about the original objections, the meet and confers[2] between the parties over the past two weeks regarding Plaintiffs' document requests have been productive in clarifying the intended scope of those requests.[3] They have resulted in Plaintiffs' commitment to narrow certain document requests and to endeavor to narrow others upon the production by the Manufacturing Defendants of certain information.[4] The parties intend to have additional meet and

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[2] The parties have met and conferred on the document requests and objections for a total of nine hours spread across six meetings: one and a half hours on November 4; one hour on each of November 5, 6, and 7; one and a half hours on November 8; and three hours on November 14.

[3] So as not to burden this letter with argument about the scope of Plaintiffs' document requests, the Manufacturing Defendants refer the Court to their response brief regarding Plaintiffs' assertions about their so-called "boilerplate" objections, which will be filed later today. However, examples of the overbreadth and ambiguity of Plaintiffs' document requests include requests for "all testing" ever performed or "that was considered but not performed" at any time on valsartan, without any limitation to the types of testing used to identify impurities generally or capable of detecting NDMA or NDEA specifically, *see* Dkt. 290-2 at ¶ 44, and requests for "*all* documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan," despite the fact that—according to their own allegations and the FDA's investigation—the potential for NDMA or NDEA formation is a result of certain specific reactions in the API manufacturing process, *see id.* ¶ 19. (emphasis added).

[4] Many of Defendants' amended objections account for and incorporate Plaintiffs' clarifications about the scope of their requests, and their commitments to narrow those requests. Others remove certain objections based on Plaintiffs' explanation of the intended scope of the request. For example, ZHP's amended objection to Request No. 19—which requests "all documents with regard to the manufacturing process for the active pharmaceutical ingredients in valsartan, including any modifications thereto"—includes the following:

> during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties' agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents

confers in the coming weeks regarding Plaintiffs' document requests, and may further narrow issues for the Court to resolve at the hearing on December 11.

In light of the ongoing nature of the meet and confers—the last of which ended at 4:00 p.m. on Thursday, November 14—the Manufacturing Defendants informed Plaintiffs that they would serve their amended objections on Monday, November 18 and asked whether Plaintiffs would agree to defer argument on the objections, if still necessary, until December 11. *See* Exhibit A (attaching email correspondence). Notwithstanding their explicit acknowledgment of the overbreadth and ambiguity of their document requests,[5] and ignoring the productivity of the meet and confers in potentially narrowing those requests, Plaintiffs responded that the amended objections would be untimely and that they insist that the Court hear argument on their request to strike the original objections on November 20. *See id.* Apparently, Plaintiffs intend to argue that the Manufacturing Defendants waived the right to amend their objections by not serving such amended objections on November 13, a date the Manufacturing Defendants originally proposed. However, the parties previously agreed to reschedule a meet and confer on certain document requests from November 12 to November 14, and to hold all-day meet and confers regarding ESI on November 15, which warranted the Manufacturing Defendants' serving their amended objections today.[6] To accommodate Plaintiffs' claimed concern about having to digest

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and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

[5] In contrast to their document requests, during the meet and confer process Plaintiffs' counsel sent the Manufacturing Defendants a letter identifying a number of specific categories of documents Plaintiffs' intended to capture with their document requests. *See* Dkt. 296 at 2 n.1 (Plaintiffs' Letter Response on Macro Discovery Issues); *see also* Exhibit B (attaching letter). Their letter betrays the obvious: Plaintiffs could have, and should have, used the information they received through Core Discovery to draft narrower and more focused document requests.

[6] Furthermore, most of the Manufacturing Defendants' objections overlap with the macro discovery issues, namely: (1) the extent of discovery regarding foreign regulatory materials and communications; (2) the extent of discovery regarding foreign sales, marketing, and agreements; (3) the extent of discovery regarding each applicable defendant's finished dose manufacturing process; (4) the extent of discovery regarding valsartan testing; (5) whether health risk discovery should be limited to the injuries alleged in the master and other complaints; (6) the relevant time period for the custodial search and production of responsive documents as to each defendant. It simply makes no sense for Plaintiffs to argue that the Manufacturing Defendants did not identify

Defendants' amended objections by the November 20 hearing, the Manufacturing Defendants proposed deferring a hearing on Plaintiffs' motion regarding their original objections until December 11, but Plaintiffs rejected that proposal without any basis.

Given the undeniable productivity of the meet and confer process regarding the scope of Plaintiffs' document requests, which is ongoing, and given the amendment of the Manufacturing Defendants' objections incorporating the commitments made during those meet and confers, the Manufacturing Defendants assert that the question whether their original objections are boilerplate is moot. However, should Plaintiffs request that the amended objections also be stricken, the Manufacturing Defendants respectfully request that the Court consider the amended objections timely served and defer any argument on them until the hearing on December 11, so that the parties may further narrow the specific discovery disputes the Court should address at that hearing.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)

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their objections with sufficient specificity, when the parties are exchanging extensive briefs on those very topics.